Don't Throw the Baby Out with the Bathwater

Smoking is the leading cause of preventable disease and death in the United States and globally.

If properly and fairly regulated ENDs could have a significant impact in reducing the use of the combustible cigarette. FDA should seek to maximize ENDS benefits while minimizing ENDS harms.

CTP Director Zeller has made regulation of tobacco (and nicotine) **based on risk, relative risk and intended use of the product (continuum of risk) a major priority of the FDA's Center for Tobacco Products.** Any regulations that are developed for ENDS of other products should be developed with that in mind. Not all ENDS products carry the same risk profile and given this rapidly changing environment if properly and flexibly regulated we could see a new generation of products in the near future.

Setting up **excessive barriers and disincentives** to developing and allowing the marketing of science-based lower risk products into the marketplace could have potential **negative health consequences** for achieving public health goals and objectives.

Regulations should be commensurate with the risks associated with the product, using the combustible cigarette as the reference product.

The focus of the regulation should be that:

- Children and adolescents should **not be able to buy or use any tobacco or nicotine products**;
- **Product standards**, including child proof packaging, and labeling and marketing requirements should be developed to achieve public health and safety objectives but not be so onerous as to be a disincentive for developing science-based lower risk products;
- Advertising and marketing **should not target those under the age of 21** and should be truthful and non-misleading. Sales of ENDS to anyone under a minimum age of sale should be strictly prohibited and enforced. Sale and distribution of ENDS through the internet should be monitored and regulated;
- Flavors are not necessarily bad especially when focused on achieving adult consumer acceptability for science-based lower risk products. **Manufacturers and marketers should avoid using any flavor descriptors that target and entice youth**;
- It is critical that the FDA/CTP should work closely with regulated manufacturers and other stakeholders in **monitoring** how products are being used and whether marketing of such products are having unintended consequences (i.e. are children and youth being influenced);
- **A more collaborative approach to the scientific study** of ENDS should be undertaken involving academic research institutions, public health authorities, regulatory authorities, and manufacturers;
- **There must be a concerted and coordinated effort to educate the public, consumers, health care professionals, policy makers, regulators, trade associations** and the media about ENDS and the potential role they could play in reducing disease and death caused by the use of tobacco products but in particular the combustible cigarette. ENDS should not be actively marketed to recruit new users of nicotine. **FDA should take a major role in ensuring that the information the public is receiving is truthful and accurate**.